

NEPHROLOGY

NEWS & ISSUES

New iron drugs could be big winners after bundle is finalized

From January 2010

by: Thomas Keating

Since U.S. regulators approved AMAG Pharmaceutical Inc.'s Feraheme in June, few nephrologists have used the new drug, but they are "on the verge" of doing so, a survey re-released Nov. 23 by BioTrends Research Group showed.

Feraheme was approved by the U.S. Food and Drug Administration for intravenous use as an iron-replacement therapy for the treatment of iron deficiency in adult patients.

With the inclusion of the very expensive medication Epogen (EPO) in the proposed ESRD bundled payment, dialysis providers could recommend to doctors that they prescribe lower doses of EPO to patients, and more iron drugs like Feraheme.

Only 8% of nephrologists reported using Feraheme in chronic kidney disease patients not on dialysis, the survey showed. However, two of the nephrologists in the study reported that their dialysis units now have a contract with AMAG and are getting ready to start using Feraheme; others report their dialysis units are considering using the product.

And, in addition to impacting other IV iron products, nephrologists expect Feraheme will increase their overall use of IV iron and reduce their use of ESAs, the survey showed. The desire to reduce use of ESAs is particularly high with the recent release of TREAT and the advent of bundling.

Rockwell Medical Inc.'s would-be Feraheme competitor, Soluble Ferric Pyrophosphate (SFP), completed FDA Phase 2b trials Oct. 29 and has entered into Phase 3. The company announced new data Nov. 2 at the American Society of Nephrology meeting in San Diego, and feels that SFP will fare very well with the final structure of the ESRD bundle.

"We do expect to see efforts made by providers to reduce EPO use, due to the bundled payment structure," Rob Chioini, president & CEO of Rockwell Medical, told NN&I. "We cannot predict if total iron use will increase as a result and we are not concerned about it as it relates to SFP. SFP is designed to be used in every treatment, like EPO, and we expect SFP dose frequency will reduce EPO use."

But, unlike the recently-launched Feraheme, SFP's introduction is a few years away. Based on the clinical work still scheduled to be completed, Chioini said he estimates SFP will be available commercially in 2013, provided it receives FDA market approval.

Rockwell Medical has licensed exclusive worldwide rights to manufacture and sell SFP and has secured patents for SFP in multiple countries, including the three largest dialysis markets in the world: the United States, Japan, and the European Union. Based on current market data, the U.S. dialysis market for IV iron is approximately \$560 million annually, while global market potential is approximately \$850 million.

And with the bundle's favorable structure toward iron drugs, U.S. market potential seems likely. The bundle will have been in effect for two years by 2013. Chioini said the bundle-as it relates to SFP and Rockwell Medical-will be "a very favorable event."

Fresenius CEO Lipps to step down in 2013

Fresenius Medical Care said in early December that Rice Powell will succeed long-time CEO Ben Lipps after 2012.

The dialysis provider said that Lipps' contract as chairman of the management board and company CEO was extended to Dec. 31, 2012. Powell has been promoted to deputy chairman of the Fresenius Medical Care Management Board and CEO of Fresenius Medical Care North America and will take over Lipps' duties effective Jan. 1, 2013.

Powell has been with the company since 1997, and has been the co-CEO of Fresenius Medical Care North America and CEO of the Renal Therapies Group. He has been a member of the Fresenius Medical Care Management Board since 2004 and has more than 30 years of experience in the health care industry.

Mats Wahlstrom, co-CEO of Fresenius Medical Care North America and a member of the Fresenius Medical Care Management Board, said he will reduce his full-time responsibilities effective January 2010.

APP Pharma's CEO retires

Thomas Silberg, president and chief executive officer of APP Pharmaceuticals Inc, retired from the company effective Dec. 31.

John Ducker, a member of the management board of Fresenius Kabi Pharmaceuticals Holding Inc.-the parent company of APP Pharma-was named by the board as new president and chief executive officer beginning January 2010.

Cantel Medical reports 85% increase in net income for quarter

High demand for face masks in response to the H1N1 flu outbreak pushed net income up 85% for

Cantel Medical Corp. in the first quarter, the company said Dec. 9.

The company's strongest performance was in the health care disposables segment where operating profit more than doubled, driven by atypically high demand for its U.S.-manufactured, U.S. Food and Drug Administration-cleared face masks in response to the H1N1 flu outbreak.

Pa. dialysis company sues UPMC Health Plan over bills

Western Pennsylvania Medical Associates, which operates seven dialysis clinics in the state, filed a federal lawsuit against UPMC Health Plan, alleging that it is owed more than \$1.7 million in unpaid claims, the Pittsburgh Post-Gazette reported Dec. 6.

Western Pennsylvania Medical Associates said that it negotiated rates for dialysis claims with UPMC Health Plan in 2006. However, according to the lawsuit, bills for dialysis have gone unpaid, or the payments have been reduced with no stated reason.

The company claims it has made numerous phone calls and submitted written inquiries about the unpaid bills, but UPMC Health Plan has failed to respond. The lawsuit includes claims for breach of fiduciary duty, breach of contract, and bad faith.

Dialysis industry concerned with Medicare shakeup proposal

Shares of DaVita Inc. tumbled as much as 3.4% Dec. 8 after the Senate discussed opening Medicare to people ages 55 to 64, a move that sparked concern from dialysis centers.

On Dec. 12, Kidney Care Partners (KCP), a consortium of dialysis providers and advocates, sent a letter to all U.S. senators in an effort to stop the proposed legislation. "We are very concerned about the potential adverse impact that this would have on ESRD patients," wrote KCP chairman and CEO of DaVita, Kent J. Thiry. The group argued current Medicare payments are inadequate to support many dialysis centers and even the smallest shift in patients from private payers to Medicare could be financially damaging. "The average dialysis clinic treats 70 patients, 90% of which are paid for by Medicare," the letter continued. "The remaining 10%, averaging seven patients, provide the crucial cross-subsidization to keep many dialysis centers open." As of Dec. 14, the proposal reportedly did not have the 60-vote backing needed from senators.

Taking Stock				
PROD/SERVICES	11/13/09	12/14/09	Change	% Change
BaxterIntl (BAX)	\$54.82	\$58.94	\$4.12	7.5%
CantelMedical (CMN)	\$17.98	\$20.52	\$2.54	14.1%
Church&Dwight (CHD)	\$58.49	\$60.33	\$1.84	3.1%
DaVita (DVA)	\$58.23	\$60.38	\$2.15	3.7%
DialysisCorp (DCAI)	\$7.70	\$7.40	-\$0.30	-3.9%
FresMedCare (FMS)	\$53.52	\$53.94	\$0.42	0.8%
Nephros (NEPH)	\$1.18	\$0.90	-\$0.28	-23.7%
NxStageMed (NXTM)	\$6.30	\$7.79	\$1.49	23.7%
RockwellMed (RMTI)	\$6.42	\$6.38	-\$0.04	-0.6%
Spire (SPIR)	\$4.56	\$4.49	-\$0.07	-1.5%
PHARMA				
AbbottLabs (ABT)	\$52.95	\$53.78	\$0.83	1.6%
AMAGPharma (AMAG)	\$42.44	\$36.25	\$6.19	-14.6%
Amgen (AMGN)	\$55.41	\$56.86	\$1.45	2.6%
GenzymeCorp (GENZ)	\$49.28	\$49.98	\$0.70	1.4%
Shire (SHPGY)	\$59.80	\$58.31	-\$1.49	-2.5%
WatsonPharma (WPI)	\$35.96	\$38.65	\$2.69	7.5%

Amgen accused of improper sale of Epogen

A former regional sales manager for Amgen, Inc. filed a lawsuit in November in Texas federal court claiming that salespersons dictated dosages of Epogen to increase the drug maker's bottom line.

Ivey Woodard alleges that he and other sales representatives often were allowed by dialysis clinics to act essentially as doctors by dictating the dosages of the anemia drug.

Woodard accuses DaVita, Inc. and Fresenius Medical Care of prescribing excessive Epogen doses to defraud Medicare out of an estimated \$1,500 to \$2,000 per injection.